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34 AMENDMENT

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International Preliminary Examination Authority
EUROPEAN PATENT OFFICE
Branch at the Hague
Patentlaan 2
Postbus 58 18
NL-2280 HV Rijswijk
THE NETHERLANDS

4 July 2005

Dear Sirs

International Patent Application No. PCT/GB2004/005313

In the name of: BIOQUELL UK LIMITED

Representative's Ref: P64961WO00

I refer to the above International application and to the Written Opinion of the International Searching Authority of 30th March 2005. I am now in a position to respond on behalf of the applicants.

I enclose the following further documents for this case:

- (i) Demand form for International Preliminary Examination under PCT Article 31;
- (ii) PCT fee calculation sheet;
- (iii) Debit order in payment of the examination and handling fees;
- (iv) New description pages 1, 1a, 1b and 3 to replace description pages 1 and 3 at present on file;
- (v) New claims 1 to 11 to replace the claims at present on file;
- (vi) A leaflet disclosing the Bioquell "Microflow Advanced Bio Safety Class II cabinet.

This invention relates to cabinets in which there is a main chamber in which a process is carried out under sterilised or aseptic conditions. A leaflet published on 1 October 2002 is enclosed which describes and illustrates one such cabinet known as the Microflow Advanced Bio Safety Class II cabinet manufactured and distributed by BIOQUELL UK Limited. The main chamber has a plenum chamber through which air can be supplied to the main chamber with a down flow filter dividing the plenum chamber from the main chamber to remove particles from and sterilise the air before the air reaches the main chamber. To deal with this problem the present inventors have provided an outlet from the plenum chamber through which sterilant vapour from the main chamber may be drawn via the filter between the main and plenum chambers and thence through the plenum chamber to the outlet thereby sterilising the

plenum chamber. Thus air supplied to the main chamber via the plenum chamber is not contaminated by bacteria lodged in the plenum chamber.

The applicants' apparatus has the following further features and advantages:

1. The active vapour is distributed throughout the whole of the interior spaces of the enclosure including the plenum above the main downflow filter.
2. There is an exhaust filter through which the vapour/gas mixture being exhausted from the enclosure must pass through before it leaves the enclosure. This usually forms part of the plenum and there are therefore two filter systems attached to the plenum. The vapour is passed through this exhaust filter to render it safe.
3. The invention not only solves the problem of bio-decontaminating the plenum chamber but also renders both of the down flow and exhaust filter systems safe so that they may be changed by an engineer.
4. By drawing continually off a small amount of vapour from the enclosure the pressure inside the chamber is reduced below that of the surrounding environment thus preventing uncontrolled escape of the active vapour which could present a hazard.
5. The exhaust filter system may consist of either one or two filters. When two filters are used they are arranged in series to that all of the air/vapour mixture passes through both filters. This double filter system is used to ensure the removal of highly hazardous material.
6. The main downflow filter is decontaminated by exposing both surfaces with the sterilising vapour and ensuring good vapour distribution both by extracting some of the vapour and also by the action of a fan attached to the vaporiser.

I believe that the applicants' main claim as now amended is clearly distinguished from the prior art cited in the International Search Report by the provision of the arrangement for withdrawing gas from the plenum chamber which causes a flow of sterilant vapour from the main chamber through the filter and then through the plenum chamber to the outlet from the plenum chamber where the sterilant vapour is filtered to render the sterilant safe for discharge to atmosphere.

I look forward to receiving an examination report regarding the allowability of this case in due course.

Yours faithfully

Geoffrey C Bayliss
Representative for the Applicants

Encl

638235; GCB; CAR

Apparatus for Bio-decontamination of Enclosures

This invention relates to apparatus for the bio-decontamination of enclosures and in particular small
5 enclosures.

US-A-5,229,071 discloses a batch method and apparatus for controlled release of gaseous air contaminants into the atmosphere through catalytic oxidation while minimizing both
10 the energy required and the volume of waste gas exhausted into the atmosphere. The device has a recirculating gas stream driven by a recirculation fan which moves gas, normally and naturally present at start-up, through a bed of granular catalyst, in an oxidizer and into contact with the
15 surface of a process-gas heater and back to the recirculation fan. The gaseous contaminants may be drawn into this system using a vacuum pump.

US-A-5,160,700 discloses a sterilizing system including a
20 sealed container for holding a gaseous sterilant under pressure and a first enclosure made at least partially of a gas-permeable material. The container and the articles to be sterilized are disposed in and sealed within the first enclosure, and the container, while in the sealed first
25 enclosure, is manipulated to release gaseous sterilant into the sealed first enclosure. A second enclosure in which the first enclosure is disposed is constructed such that the sterilant released into the first enclosure from the container diffuses through the gas-permeable material of the
30 first enclosure into the second enclosure at a rate capable of establishing sterilizing conditions in the first enclosure during a sterilizing cycle to thereby effect

sterilization of the articles in the first enclosure. A moisture-releasing humidifying device is disposed within the first enclosure for releasing moisture into the first enclosure during the sterilization cycle and a regulating system comprising an exhaust device is operable to exhaust the sterilant gas from the second enclosure to minimize the amount of sterilant gas in the second enclosure, thereby providing for minimized residue sterilant in the surrounding work area.

10 US-A-2003/0086820 discloses that a surface which carries a material which is infected with prions is cleaned with an alkaline cleaning solution to remove as much proteinaceous material as possible from the surface. The solution contains an alkaline cleaning agent which attacks prions remaining on the surface and which also attacks prions removed from the surface during the cleaning step. After the cleaning step, the surface is exposed to a strong gaseous oxidant, preferably hydrogen peroxide vapor. The 15 hydrogen peroxide or other strong oxidant attacks the prions, particularly the unclumped prion strands, deactivating the prions.

20 US-A-3,503,703 discloses a sterilizing apparatus having a gas impermeable barrier and a flexible, collapsible gas impermeable bag having an aperture for receiving articles to be sterilized adapted to be mounted in gastight connection with the barrier. The bag is connected to the barrier in a gastight relationship and exhaust means are provided for 25 reducing the internal pressure in the bag and for circulating air in the bag and valving and controls are provided for carrying out a sterilizing cycle in the bag.

Small enclosures are typically up to about 2m³ in volume, and include but are not limited to Class II Microbiological Safety Cabinets (MSC). Our International Patent Application 5 PCT/GB03/001386 discloses methods of bio-decontaminating larger enclosures such as rooms or chambers by placing an apparatus to generate the fumigant gas inside the chamber. The technique described works well for rooms and large chambers of a simple nature but is not specifically intended 10 to deal with the problems associated with Class II microbiological safety cabinets and similar enclosures.

The standard technique for bio-decontaminating a Class II MSC is to boil formalin to generate formaldehyde vapour. For 15 this method to be effective substantial amounts of formalin have to be evaporated, the European Standard EN BS 12469 requires 60ml of formalin plus 60ml of water to be evaporated for each cubic metre of enclosure volume. Other authorities use smaller amounts of liquid but all of the 20 methods used generate considerable amounts of condensation within the MSC and also form deposits of paraformaldehyde.

Formalin gassing of an MSC has a number of disadvantages; firstly it leaves a residue of formalin and paraformaldehyde 25 that can only be removed by long periods of aeration; secondly the bio-decontamination process is slow, the normal exposure time being eight hours; thirdly it is difficult to

the process is very fast. Many, if not most, Class II MSCs that are in use recirculate their exhaust air back to the laboratory, and hence a method is required to remove the hydrogen peroxide vapour at the end of the bio-
5 decontamination cycle.

The present invention is a technique to overcome these problems and provide a safe and reliable way to bio-decontaminate small enclosures including MSCs.

10 This invention provides an enclosure for carrying out an operation under sterile conditions comprising a main chamber containing a first apparatus disposed within the chamber for generating and delivering a sterilant vapour from a supply
15 held within the chamber to be distributed throughout the chamber to sterilise the surfaces, a plenum chamber, a filter separating the plenum chamber from the main chamber, a pump for the plenum chamber for delivering air into the plenum chamber and then through the filter to the main
20 chamber to create a filtered flow of air through the chamber and means to draw gas from the enclosure via an outlet from the plenum chamber to create a flow of sterilant vapour from the main chamber through the filter decontaminating the filter and through the plenum chamber to the outlet to
25 sterilise the plenum chamber before exiting the outlet from the plenum chamber and to maintain pressure in the main and plenum chambers below atmospheric so that any leak paths result in leakage from the atmosphere into the chambers and does not result in release of sterilant vapour to the
30 atmosphere around the enclosure.

In accordance with one embodiment of the invention the means for drawing gas from the enclosure comprise a fan located in a conduit connected to an outlet from the enclosure, the
35 conduit having means to render sterilant reaching the

CLAIMS

1. An enclosure for carrying out an operation under sterile conditions comprising a main chamber containing a
5 first apparatus disposed within the chamber for generating and delivering a sterilant vapour from a supply held within the chamber to be distributed throughout the chamber to sterilise the surfaces, a plenum chamber, a filter separating the plenum chamber from the main chamber, a pump
10 for the plenum chamber for delivering air into the plenum chamber and then through the filter to the main chamber to create a filtered flow of air through the chamber and means to draw gas from the enclosure via an outlet from the plenum chamber to create a flow of sterilant vapour from the main chamber through the filter decontaminating the filter and through the plenum chamber to the outlet to sterilise the plenum chamber before exiting the outlet from the plenum chamber and to maintain pressure in the main and plenum chambers below atmospheric so that any leak paths result in
15 leakage from the atmosphere into the chambers and does not result in release of sterilant vapour to the atmosphere around the enclosure.
2. An enclosure as claimed in claim 1, wherein the means
25 for drawing gas from the enclosure comprise a fan located in a conduit connected to an outlet from the enclosure, the conduit having means to render sterilant reaching the conduit ineffective to avoid release of sterilant to atmosphere.

3. An enclosure as claimed in claim 2, wherein the means to render the sterilant ineffective are located upstream of the fan in relation to the enclosure.
- 5 4. An apparatus as claimed in claim 3, wherein the means to render the sterilant ineffective comprise a catalytic converter for breaking the sterilant down into harmless biproducts which can be exhausted to atmosphere.
- 10 5. An enclosure as claimed in claim 3 or claim 4, wherein the conduit has selectively operable valve controlled outlets of larger and smaller capacities, the smaller capacity outlet being open during said period when the enclosure is to be maintained at a predetermined reduced pressure and the larger valve controlled outlet being opened during discharge of the sterilant atmosphere from the enclosure.
- 15 6. An enclosure as claimed in any of the preceding claims wherein the enclosure has a main chamber containing said apparatus for producing sterilant vapour and within which the operation to be carried out in the chamber is performed and a plenum chamber separated from the main chamber by a filter, the plenum chamber having a pump for delivering air into the plenum chamber through the filter to the main chamber to create a filtered flow of air through the chamber and the means for drawing gas from the chamber remote from the first apparatus is connected to the plenum chamber.
- 20 7. An enclosure as claimed in claim 6, wherein a filter is provided in the outlet from the plenum chamber to the means for drawing gas from the plenum chamber.

8. An enclosure as claimed in any of the preceding claims, wherein the enclosure contains a second apparatus for rendering sterilant in the atmosphere in the chamber 5 ineffective after the sterilisation of the chamber.

9. An enclosure as claimed in claim 8, wherein the means for rendering sterilant ineffective comprises a housing containing a catalytic converter for converting the 10 sterilant into harmless biproducts for disposal and means for circulating the atmosphere of the chamber through the housing to reduce the sterilant concentration in the atmosphere when the sterilisation operation has been performed.

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10. An enclosure as claimed in any of the preceding claims, wherein the outlet from the plenum chamber contains an exhaust filter through which air/sterilant vapour is drawn from the chamber.

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11. An enclosure as claimed in claim 10, wherein the outlet from the plenum chamber contains two spaced filters through which sterilant vapour is drawn from the plenum chamber.

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511707; GCB; VAT